

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Abraham J. Domb

Serial No.:

10/763,876

Art Unit:

Not Yet Assigned

Filed:

January 23, 2004

Examiner:

Not Yet Assigned

For:

POLYMERIC FORMULATIONS FOR DRUG DELIVERY

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicant submits an Information Disclosure Statement, including three (3) pages of Form PTO-1449. Most of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 10/433,143, filed May 30, 2003, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

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INFORMATION DISCLOSURE STATEMENT

# U.S. Patents

Number	Issue Date	<u>Patentee</u>	Class/Subclass
4,999,417	03-12-1991	Domb	528/271
5,171,812	12-15-1992	Domb	526/318.2
5,179,189	01-12-1993	Domb, et al.	528/271

# **Foreign Documents**

Number	<b>Publication Date</b>	<u>Patentee</u>	Country
0 598 131	05-25-1994	Kansai Paint Co., Ltd.	EP
WO 93/05096	03-18-1993	Nova Pharm Corp.	PCT
WO 96/22270	07-25-1996	Yissum Res. Dev. Co.	PCT

#### **Publications**

BREMER & OSMUNDSEN, "Fatty acid oxidation and its regulation," in <u>Fatty Acid Metabolism and Its Regulation</u> (Numa, ed.) Elsevier: New York, p. 113-154 (1984).

DANG, et al., "Effects of GLIADEL wafer initial molecular weight on the erosion of wafer and release of BCNU," J. Control. Rel. 42: 83-92 (1996).

DOMB & LANGER, "Polyanhydrides. I. Preparation of high molecular weight polyanhydrides," *J. Polym. Chem.* 25: 3373-3386 (1987).

DOMB & MANIAR, "Absorbable biopolymers derived from dimer fatty acids," J. Polym. Sci. Polymer Chem. 31: 1275-1285 (1993).

DOMB, et al., "Poly(anhydrides). 3. Poly(anhydrides) based on aliphatic-aromatic diacids," *Macromolecules* 22: 3200 (1989).

DOMB, et al., "Polyanhydrides" in <u>Handbook of Biodegradable Polymers</u> (Domb, et al., eds.) Hardwood Academic Publishers, p. 135-159 (1997).

DOMB, et al., "Polyanhydrides as carriers of drugs" in <u>Biomedical Polymers: Designed-to-Degrade Systems</u> (Shalaby, ed.) Hanser Publishers: Munich, p. 69-96 (1994).

GOPFERICH, in <u>Handbook of Biodegradable Polymers</u> (Domb, et al., eds.) Hardwood Academic Publishers, p. 451-471 (1997).

HELLER, "Biodegradable polymers in controlled drug delivery," CRS Crit. Rev. Ther. Drug Carrier Syst. 1: 39-90 (1984).

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HOPFENBERG, "Controlled release from erodible slabs, cylinders, and spheres" in Controlled Release Polymeric Formulations (Paul, et al., eds.) ACS Symposium Series, Washington DC, 33: 26-32 (1976).

LEONG, et al., "Polyanhydrides for controlled release of bioactive agents," *Biomaterials* 7: 364-371 (1986).

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TEOMIM, et al., "Ricinoleic acid-based biopolymers," J. Biomed. Mater. Res. 45: 258-287 (1999).

TEOMIM, et al., "Fatty acid terminated polyanhydrides," J. Polym. Sci. 37: 3337-3344 (1999).

TIROSH, et al., "Oxidative stress effect on the integrity of lipid bilayers is modulated by cholesterol level of bilayers," *Chemistry and Physics of Lipids* 87: 17-22 (1997).

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# Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicant invites the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicant is of the opinion that his claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,

Patrea L. Pabst

Reg. No. 31,284

Dated: April 8, 2004

HOLLAND & KNIGHT LLP One Atlantic Center 1201 West Peachtree Street, N.E. Suite 2000 Atlanta, Georgia 30309-3400 404-817-8473 FAX 404-817-8588 www.hklaw.com

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# Certificate of Mailing under 37 C.F.R. § 1.8(a)

I hereby certify that this Information Disclosure Statement, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date shown below with sufficient postage as first-class mail in an envelope addressed to the Assistant Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date:

April 8, 2004

Erica C. Boughner

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NFORMATION DISCLOSURE OF THE STATEMENT BY APPLICANT OF THE AST MANY Sheets as necessary)	Application Number	10/763,876
13 E	Filing Date	January 23, 2004
	First Named Inventor	Abraham J. Domb
	Group Art Unit	
Category & Charles	Examiner Name	
Sheet 1 of 3	Attorney Docket Number	PG 102

U.S. PATENT DOCUMENTS										
Examiner Initials*							US Patent Document	Name of Patentee or Applicant of Cited Document	Date of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code <sup>2</sup> (if known)								
		4,999,417	Domb	03-12-1991						
		5,171,812	Domb	12-15-1992						
		5,179,189	Domb, et al.	01-12-1993						
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-			F	OREIGN PATENT DOCUMENT	S		
 Cite No.¹			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>	
	Office.3	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)		·		
	EP	0 598 131		Kansai Paint Co., Ltd.	05-25-1994		
	PCT	WO 93/05096		Nova Pharm Corp.	03-18-1993		
	PCT	WO 96/22270		Yissum Res. Dev. Co.	07-25-1996		
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application.

<sup>&</sup>lt;sup>1</sup> Unique citation designation number <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 6 Applicant to place a check mark here if English language Translation is attached.

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	STATI	MENT	N DISCLOSURE BY APPLICANT heets as necessary)	Application Number	10/763,876	
				Filing Date	January 23, 2004	
				First Named Inventor	Abraham J. Domb	
				Group Art Unit		
				Examiner Name		
Sheet	T	F -	3	Attorney Docket Number	PG 102	

Examiner's	Cite	OTHER ART NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the	Τ²
Initials*	No.'	item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	Ľ
		BREMER & OSMUNDSEN, "Fatty acid oxidation and its regulation," in <u>Fatty Acid Metabolism and Its Regulation</u> (Numa, ed.) Elsevier: New York, p. 113-154 (1984).	
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		GOPFERICH, in <u>Handbook of Biodegradable Polymers</u> (Domb, et al., eds.) Hardwood Academic Publishers, p. 451-471 (1997).	-
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		HOPFENBERG, "Controlled release from erodible slabs, cylinders, and spheres" in <u>Controlled Release Polymeric Formulations</u> (Paul, et al., eds.) ACS Symposium Series. Washington DC, 33: 26-32 (1976).	$\vdash$

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	Substitute fo	or form 144	19A/PTO	. Complete if Known		
	STATI	EMENT	ON DISCLOSURE BY APPLICANT heets as necessary)	Application Number	10/763,876	
•				Filing Date	January 23, 2004	
				First Named Inventor	Abraham J. Domb	
				Group Art Unit		
				Examiner Name		
Sheet	3	of	3	Attorney Docket Number	PG 102	

		OTHER ART NON PATENT LITERATURE DOCUMENTS	
Examiner's Initials*	Cite No.¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
		LEONG, et al., "Polyanhydrides for controlled release of bioactive agents," <i>Biomaterials</i> 7: 364-371 (1986).	
		MÄDER, et al., "In vitro/in vivo comparison of drug release and polymer erosion from biodegradable P(FAD-SA) polyanhydrides — a noninvasive approach by the combined use of electron paramagnetic resonance spectroscopy and nuclear magnetic resonance imaging," <i>Pharm. Res.</i> 14(6): 820 (1997).	
		PARK, et al., "Biodegradable polyanhydride devices of cefazolin sodium, bupivacaine, and taxol for local drug delivery: preparation, and kinetics and mechanism of in vitro release," J. Control. Rel. 52: 179-189 (1998).	
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		TEOMIM, et al., "Ricinoleic acid-based biopolymers," J. Biomed. Mater. Res. 45: 258-287 (1999).	
		TEOMIM, et al., "Fatty acid terminated polyanhydrides," <i>J. Polym. Sci.</i> 37: 3337-3344 (1999).	
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